

PRIA. Particularly, small facilities that operate in small niche markets may incur large expenses finding new suppliers.

(Response) FDA did not include in the Preliminary Regulatory Flexibility Analysis the cost of small entities losing foreign suppliers. FDA has estimated that 16 percent of foreign facilities may stop exporting to the United States to avoid the registration requirements. FDA estimates that the impact of registration on the number of line entries submitted for import into the United States will be less than 2 percent of all food entries. This may result in a significant impact on a substantial number of small entities. However, FDA is not able to predict how many small entities will be adversely affected or the size of the impact, and none of the comments provided a basis from which to estimate this impact.

Of the 216,271 domestic entities covered under the interim final rule, 99 percent are small according to the Small Business Administration's (SBA's) regulations. The expected burden for small entities is low, between \$90 and \$147. For some small facilities, however, costs may be much higher than the expected burden. As stated previously, there is a potential for large transaction costs associated with finding new trading partners. Also, some small facilities may experience unusual difficulties in registering, such as difficulty understanding the requirements, difficulty finding the registration form or website, or confusion over whether they are required to register. With such a large number of facilities affected, if a meaningful percentage of small entities experience a much larger burden, a substantial number of small entities will experience a significant economic effect. A discussion of options considered for small entities was included in the proposed rule. Additional options are also considered in the final regulatory impact analysis, which may also be considered an analysis of options for small businesses because the vast majority of affected entities are small.

VI. Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4) requires cost-benefit and other analyses before any rulemaking if the rule would include a "Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any 1 year." The current inflation-adjusted statutory threshold is \$113 million. FDA has determined that this

interim final rule does not constitute a significant rule under the Unfunded Mandates Reform Act.

VII. Small Business Regulatory Enforcement Fairness Act (SBREFA) Major Rule

The Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-121) defines a major rule for the purpose of Congressional review as having caused or being likely to cause one or more of the following: An annual effect on the economy of \$100 million; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with the SBREFA, the Office of Management and Budget (OMB) has determined that this interim final rule is a major rule for the purpose of Congressional review.

VIII. Paperwork Reduction Act of 1995

This interim final rule contains information collection requirements that are subject to review by OMB under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520). The title, description, and respondent description of the information collection provisions are shown later with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Registration of Food Facilities.

Description: The Bioterrorism Act contains a provision requiring the Secretary to issue a regulation requiring that domestic and foreign facilities that manufacture/process, pack, or hold food intended for consumption in the United States register with FDA by December 12, 2003. Under the Bioterrorism Act, a foreign facility is one that manufactures/processes, packs, or holds food for consumption in the United States without further processing or packaging outside the United States. Information FDA requires on the registration form includes the name and full address of the facility; emergency contact information; all trade names the facility uses; applicable food product categories identified in § 170.3, unless "most/all" human food categories "or none of the above mandatory categories" is checked; and a certification statement that includes the name of the individual authorized to submit the registration form. Additionally, under the interim

final rule, facilities would be encouraged to submit their preferred mailing address; type of activity conducted at the facility; food categories not included under § 170.3, but which are helpful to FDA for responding to an incident; type of storage, if the facility is primarily a holding facility; and approximate dates of operation if the facility's business is seasonal. Under the interim final rule, facilities would also be required to submit timely updates within 60 days of a change to any required information on their registration form, and are required to cancel their registration when the facility ceases to operate or is sold to new owners or ceases to manufacture/process, pack, or hold food for consumption in the United States.

Description of Respondents: Domestic facilities that manufacture/process, pack, or hold food for consumption in the United States are required to register. Foreign facilities are required to register if they manufacture/process food for consumption in the United States that is not further processed or packaged before being shipped to the United States or if they pack or hold such food. A food is not considered to have been further processed solely because labeling was added or other *de minimis* activity was performed with respect to the food.

TABLE 17.—NO. OF RESPONDENTS

Domestic facilities	216,271
Foreign facilities	205,405
Total	421,676

Burden: In the PRA analysis of the proposed rule, FDA estimated that it would take an administrative worker with Internet access 1 hour to read and understand the registration requirements; this time was doubled to 2 hours of an administrative worker's time for those facilities without Internet access. In response to comments, FDA has revised this estimate to 1 or 2 hours of a manager's time to read and understand the regulations. Foreign facilities' workers would need 1 hour to read and understand the registration requirements, if they have access to the Internet and can read and write in English. An additional 5 hours would be needed if they do not have Internet access, and an additional 5 hours would be needed if they do not read or understand English. In subsequent years, facilities that enter the industry would have to register, facilities that close would have to notify FDA of their closure, and facilities that have changes in their registration information would